# UNITED STATES PATENT AND TRADEMARK OFFICE

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/788,898 | 02/26/2004 | Cornelius G. Hunter | 922_002 | 4547 |

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| EXAMINER |
|---|
| NEGIN, RUSSELL SCOTT |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/20/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

PTOL-90A (Rev. 10/06)

| | Application No. | Applicant(s) |
| | 10/788,898 | HUNTER, CORNELIUS G. |
| ***Office Action Summary*** | Examiner | Art Unit | |
| | Russell S. Negin | 1631 | |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on <u>30 November 2006</u>.

2a)☒ This action is **FINAL**.         2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-39 and 46-59* is/are pending in the application.

    4a) Of the above claim(s) *1-39, 46-48 and 50-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49 and 53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All  b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received. .

**Attachment(s)**

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

## DETAILED ACTION

### *Comments*

It is acknowledged that claims 1-39 and 46-53 are pending. It is also

acknowledged that claims 54-59 are added. Claims 49 and 53-59 are examined in this

Office action.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
> matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the
> conditions and requirements of this title.

Claims 49 and 53-59 are rejected under 35 U.S.C. 101 because the claimed

invention is directed to non-statutory subject matter.

In regards to claims 49 and 53-59, the instant claims are drawn to a computer

algorithm. A computer algorithm is non-statutory unless the claims include a step of

physical transformation, or if the claims include a useful, tangible and concrete result. It

is important to note, that the claims themselves must include a physical transformation

step or a useful, tangible and concrete result in order for the claimed invention to be

statutory. It is not sufficient that a physical transformation step or a useful, tangible, and

concrete result be asserted in the specification for the claims to be statutory. In the

instant claims, there is no step of physical transformation, thus the Examiner must

determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Claims 49 and 53-59 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or by including a physical transformation.

As stated in the section 2106 of the M.P.E.P., "The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a Sec. 101 judicial exception, in that the process claim must set forth a practical application of that Sec. 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no

substantial practical application."). "[A]n application of a law of nature or mathematical

formula to a . . . process may well be deserving of patent protection." Diehr, 450 U.S. at

187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14

L.Ed. 683 ("It is for the discovery or invention of some practical method or means of

producing a beneficial result or effect, that a patent is granted . . ."). In other words, the

opposite meaning of "tangible" is "abstract.""

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49 and 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Kamtekar et al. [Science, volume 262, 1993, pages 1680-1685] in view of Taylor

[Nucleic Acids Research, 1986, volume 14, pages 437-441] in view of Lipman et al.

[Biopolymers, Volume 26, pages 17-26, 1987].

Claim 49 and 53-59 state:

Claim 49 is a computer program product for identifying the coding region of a

nucleotide sequence and assigning symbols to each residue based on their properties.

Claim 53 is a system for identifying the coding region of a nucleotide sequence

and assigning symbols to each residue based on their properties.

Claims 54 and 57 limit the program product and system to a range of adjacent

symbols from five to fifteen.

Claims 55 and 58 limit claims 49 and 53, respectively to determination of an

expected number of significant signals in each said reading frame.

Claims 56 and 59 limit claims 49 and 53, respectively to a comparison between

the actual and expected number of signals in each said reading frame.

The paper of Kamtekar et al., entitled, "Protein design by binary patterning of

polar and nonpolar amino acids," denotes nonpolar amino acids in Figure 1B as black

circles for nonpolar amino acids (Phe, Leu, Ile, Met, or Val) and white circles for polar

amino acids (Glu, Asp, Lys, Asn, Gln, or His).  The peptides are generated from

translations of nucleic acids.  The purpose of separation and distinction of polar and

non-polar peptides in Kamtekar et al. is better efficiency in production of helix bundles.

Each helix in Figure 1 of Kamtekar et al. is composed of fourteen adjacent residues.

However, Kamtekar et al. does not teach computational translation of the reading

frames of Kamtekar et al. into proteins.  Kamtekar et al. additionally does not teach a

moving window across the polypeptides, or a generation of a signal based on the amino

acids in the window.

The article of Taylor, entitled, "A computer program for translating DNA

sequences into protein," states in its abstract, "This paper describes a comprehensive

program for translating one or two DNA sequences into amino acid sequences."  Taylor

continues in the introduction on page 437, "Various programs have been described in

the literature for protein translation...  One of these... was adapted, with a number of

corrections and enhancements, for our PDP 11/44 departmental computer and has

served several years in routine use." Figure 2 on page 439 illustrates the output of such

a program. This program is capable of translating in multiple reading frames (i.e. see

Figure 2).

However, the above-mentioned sources do not teach a moving window across

the polypeptides, or a generation of a signal based on the amino acids in the window.

The article of Lipman et al., entitled, "Local sequence patterns of hydrophobicity

and solvent accessibility in soluble globular proteins," states in the abstract:

> We examined the variation on the solvent accessibility and hydrophobicity of the amino acids
> along the sequence of 58 soluble globular proteins with known tertiary structure.

Lipman et al. continues in the introduction:

> A central problem in biochemistry and molecular biology is the relationship of amino acid
> sequence to protein structure. A useful starting point has been the observation that hydrophilic
> amino acids tend to appear on the surface of proteins while hydrophilic amino acids tend to
> appear on the surface of proteins while hydrophobic residues tend to be buried in the interior,
> relatively inaccessible to solvent. This observation has been exploited by a number of sequences
> analysis methods that use the average hydrophobicity of subsequences to predict accessibility.

On page 19 of Lipman et al., Figure 1 plots the fractional accessibility of each

residue in thioredoxin as a function of sequence position. This fractional accessibility is

indicative of the hydrophobicity of the residue in that the more accessible the residue is,

the more unlikely that it is hydrophobic.

On page 19, of Lipman et al., Figure 2 plots in a signal in the form of a histogram,

the frequency of the number of tripeptides in a protein with a given fractional

accessibility as a function of the fractional accessibility. Tripeptides are generated

computationally as every adjacent segment of three amino acids. The set of tripeptides

have overlapping regions, and therefore, a set of all of the tripeptides is interpreted as

the protein viewed through a moving window with a size of three adjacent residues.

Figure 2 also illustrates a scatter plot of an "expected" or standard signal is which the

same protein with the identical sequence has the positions of amino acids in its

sequence randomized. The frequencies of the signals at each level of fractional

accessibility are compared with that of the randomized sequence. Whether the

histogram crosses the scatter plot at a particular fractional accessibility is indicative of

an excess in the level of hydrophobicity of the protein corresponding to the fractional

accessibility being evaluated on the x-axis.

On page 24 of Lipman et al., lines 27-29 state, "...a residue is considered

exposed if the average fractional accessibility of the residue and its nearest neighbor

residues is 0.4... or above..." The value of 0.4 is considered a threshold value above

which it is hydrophilic (i.e. opened circle) and below which it is hydrophobic (i.e. closed

circle).

It would have been obvious to someone of ordinary skill in the art at the time of

the instant invention to modify Kamtekar et al. in view of Taylor in view of Lipman et al.

to result in the instantly claimed invention because while Kamtekar et al. translated

nucleotides into amino acids and classified the amino acid polarity for use in helix

bundles, Taylor has the advantage of computationally translating proteins from

nucleotide sequences at multiple reading frames for more convenient, automated

protein translation, and Lipman et al. has the advantage of using computational

methods of peptide sequence analysis in determining fractional accessibility and

hydrophobicity in order to better understand the structure of proteins and constituent

residues in terms of their interactions with solvent; in the cited portion of the introduction

of Lipman et al., Lipman et al. even sets forth an explanation to the partitioning of

hydrophobic and hydrophilic residues as seen in the helix bundles of Kamtekar et al.

## *Response to Arguments*

Applicant's arguments filed 30 November 2006 have been fully considered but

they are not persuasive.

In terms of the 35 U.S.C. 101 rejection, applicant argues on pages 17 and 18 of

the Remarks of 30 November 2006:

> The subject matter claimed in the present application therefor is clearly the kind of subject matter described in the quoted material set forth above as being in compliance with 35 U.S.C. 101 namely, subject matter in which a computer program is part of an otherwise statutory manufacture or machine.

The applicants have quoted Annex IV of the Official Gazette notice of 22

November 2005, which states:

> Computer programs are often recited as part of a claim. USPTO personnel should determine whether the computer program is being claimed as part of an otherwise statutory manufacture or machine. In such a case, the claim remains statutory irrespective of the fact that a computer program is included in the claim... When a computer program is recited in conjunction with a physical structure, such as a computer memory, USPTO personnel would treat the claim as a product claim.

This passage states that if a claim is treated as statutory, the entire claim is statutory

regardless of whether is has a computer program as part or the entirety of a claim.

However, for a claim with a computer program to be considered statutory, the Official

Gazette and section 2106 of the M.P.E.P. state that a "useful, concrete, and tangible

result" must be derived from the claim. Since the amended claims do not generate this

"useful, concrete, and tangible result," the set of claims are considered to be

nonstatutory under 35 U.S.C. 101.

Applicant's arguments considering the obviousness prior art rejections on pages

18-20 of the Remarks of 30 November 2006 have been fully considered. They are

based on the set of claims as amended and are addressed with the new grounds for

rejection.


### *Conclusion*

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Irem Yucel, Supervisory Patent Examiner, can be reached at (571) 272-0781.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSN
15 February 2007

15 February 2007

**JOHN S. BRUSCA, PH.D**
**PRIMARY EXAMINER**